

**Homeopathic Product Regulation:
Evaluating FDA's Regulatory Framework After a Quarter-Century**

Docket No. FDA-2015-N-0540

**Testimony by the American Association of Naturopathic Physicians
By Amy Rothenberg, ND, DHANP**

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Introduction

Thank you for the opportunity to speak today at this public hearing. My name is Amy Rothenberg and I am a board member of the American Association on Naturopathic Physicians (AANP), and president of the Massachusetts Society of Naturopathic doctors (MSND). Aside from maintaining a general naturopathic medical practice, I am board certified by the Homeopathic Academy of Naturopathic Physicians. I also sat on the Board of Health in Amherst, Massachusetts for six years and have recently served as vice president of the board of the Amherst Survival Center, which provides free medical care, food and clothing to people in need.

Naturopathic Medicine and Naturopathic Physicians

AANP is a national professional association representing 4,500 licensed naturopathic physicians in the United States. Our members are physicians trained as experts in natural medicine. They are trained to find the underlying cause of a patient's condition rather than focusing solely on symptomatic treatment. Naturopathic doctors (NDs) take comprehensive health histories, physical examinations, and order lab tests, imaging procedures, and other diagnostic tests. Like our medical colleagues, licensed naturopathic physicians diagnose and treat disease. NDs work collaboratively with all branches of medicine, both referring to and accepting referrals from other practitioners for diagnosis or treatment when appropriate.

NDs attend 4-year, in-residence, fulltime graduate level programs at institutions recognized by regional accrediting bodies that are, in turn, recognized by the US Department of Education. There are currently 7 such schools in North America. Naturopathic medical schools provide equivalent foundational coursework as MD and DO schools. Such coursework includes the basic sciences as well as cardiology, neurology, radiology, obstetrics, gynecology, immunology, dermatology, and pediatrics. In addition, ND programs provide extensive education unique to the naturopathic approach, emphasizing disease prevention and whole person wellness, including homeopathy.

Degrees are awarded after extensive classroom study and clinical training. In order to be licensed to practice, an ND must also pass an extensive postdoctoral exam and fulfill annual continuing education requirements. Currently, 20 states and territories license NDs and legislative efforts are underway in many other states, including my Commonwealth of Massachusetts, to obtain licensure.

Naturopathic physicians provide treatments that are effective and safe. Since they are extensively trained in pharmacology, NDs are able to integrate naturopathic treatments with prescription medications, often working with conventional medical doctors and osteopathic doctors, as well as compounding pharmacists, to ensure safe and comprehensive care.

Naturopathic physicians have practiced and taught homeopathy since naturopathic medicine was defined as a profession. We are primary care providers fully trained in homeopathic prescribing, integrating homeopathy within our medical school education, our board examinations and clinical practice.

Aside from my current positions, I cofounded the New England School of Homeopathy, the largest and oldest continuous postgraduate study of homeopathy in the United States, training physicians in the art and science of integrating homeopathy into their medical practice. I have lectured on homeopathic care widely, as for example, for the American Medical Student Association, the American Holistic Nurses Association, the Retail Clinician Education Congress (encompassing nurse practitioners and pharmacists), and at University of Massachusetts School of Medicine. This is fairly representative of the interaction that naturopathic physicians have with allied health professionals with regard to homeopathy.

Recommendations

AANP would like to respond to two particular questions posed by FDA.

Question 1: What are consumer and health care provider attitudes towards human drug and biological products labeled as homeopathic?

Naturopathic physicians are taught homeopathy in naturopathic medical schools, and use it widely in practice. Homeopathy is perceived favorably by physicians and patients, both for efficacy but especially for its safety profile. The low cost of the medicines, as well as the consistent quality of product, make them appealing to both physician and patient. The consistency and quality are preserved by the American Association of Homeopathic Pharmacists (AAHP) and the Homeopathic Pharmacopeia of the United States (HPUS), using cGMP, and taught to physicians. Over decades of use, we have not found problems or variability with quality of the homeopathic product, and no toxicity has been reported.

The experience of naturopathic physicians who use homeopathic products is consistent with other licensed physicians' reports of homeopathic use. Specifically, positive reliable effects and no toxicity, in an affordable, easy to administer, well tolerated product.

Question 4: Are there areas of the current CPG that could benefit from additional clarity? If so, please explain.

The AANP believes that FDA's CPG Sec. 400.400 Conditions Under Which Homeopathic Drugs May be Marketed, is sufficient as written. That said, we believe that the *enforcement* of those guideline should be clarified, in collaboration with the American Association of Homeopathic Pharmacists, the Homeopathic Pharmacopoeia Convention of the United States, and the AANP.

We have identified two areas that reflect a need for further clarification or compliance:

a. CPG Sec. 400.400 definition 2 states, “Drug products containing homeopathic ingredients in combination with non-homeopathic active ingredients are not homeopathic drug products.” While the definition is clear and need not change, there could be more robust enforcement here. We have found a few products that use several active ingredients, where the homeopathic drug is only one part and the rest of the active ingredients are non-homeopathic. The AANP agrees with FDA that these should not be marketed as homeopathic products.

b. CPG Sec. 400.400 background states, “Those products that are offered for treatment of serious disease conditions, must be dispensed under the care of a licensed practitioner.” People who suffer from potentially life threatening diseases, such as asthma, should be treated by health care providers. Having OTC drugs – homeopathic or otherwise – labeled in a confusing manner for consumers should be avoided. We urge that no homeopathic product be labeled with the potentially life threatening diseases, such as asthma, as a prominent feature. While this is already in the guideline and need not change, it would be wise to build in more interaction between FDA and the AAHP/HPCUS/AANP, to clarify best practices with regard to labeling guidelines.

That said, this is a potential hazard only. In decades of teaching about, prescribing for, and caring for the many thousands of patients throughout the USA, where licensed naturopathic physicians work, toxicity has never been noted. We have not found any incidents of someone using a product labeled in a potentially confusing manner go on to develop problems or have their symptoms worsen. So we are not seeking a change in current policy, only clarification.

Of particular import is having properly labeled homeopathic products stay available OTC, as a choice to the public for self-care of “self-limiting disease conditions amenable to self-diagnosis [of symptoms]” as currently described in CPG Sec. 400.400. The only change that we are recommending is more interaction between FDA and AAHP, HPCUS, and AANP to assist in compliance clarifications.

Conclusion

In summary, AANP believes that FDA’s current regulatory approach to homeopathic products is working well. The low cost of these medicines, as well as the consistent quality of product, make them appealing to both physician and patient. Over decades of use, we have not found problems or variability with quality of the homeopathic product, and no toxicity has been reported. These products should remain available to the public OTC. We do recommend certain clarifications and a closer working relationship between the FDA and AANP/AAHP/HPCUS.

Thank you for the opportunity to present these comments. We look forward to working with the FDA on similar issues in the future.

If AANP can answer any questions, please contact Michael Jawer, AANP Director of Government and Public Affairs (mike.jawer@naturopathic.org; 202-237-8150).